

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

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MASHON BAINES and NANCIE FRONING,
on behalf of themselves and all others similarly
situated,

Plaintiffs,

-against-

REPORT AND
RECOMMENDATION
CV 21-5330 (JS)(AYS)

NATURE’S BOUNTY (NY) INC., and THE
BOUNTIFUL COMPANY (NY),

Defendants.

-----X
SHIELDS, Magistrate Judge:

This is an action commenced by Plaintiffs, Mashon Baines (“Baines”) and Nancie Froning (“Froning”) (collectively “Plaintiffs”), against Defendants, Nature’s Bounty (NY) Inc. and The Bountiful Company (NY) (collectively “Defendants”). (Am. Compl., Docket Entry (“DE”) [21].) Plaintiffs allege New York and California State law claims sounding in false advertising. (*Id.*) Federal jurisdiction is alleged pursuant to 28 U.S.C. §1332(d)(2).

Plaintiffs seek to represent New York and California sub-classes of individuals who state they have been harmed by the allegedly false labeling on Defendants’ product, a dietary supplement marketed under the name “Nature’s Bounty 1400 mg Fish Oil” (the “Supplement” or the “Product”). Plaintiffs argue that the way in which the Product is processed makes the use of the name “fish oil” false. Their causes of action are as follows: (1) New York and California state law claims for breach of warranty (First Cause of Action); (2) claims alleged pursuant to Sections 349 and 350 of the General Business Law of the State of New York, N.Y. Gen. Bus. L. §§349-350 (“Section 349” and “Section 350”) (Second and Third Causes of Action alleged on behalf of a New York State sub-class); (3) claims alleging violation of the unfair competition and

false advertising laws of the State of California (Fourth, Fifth, Sixth, Seventh and Eighth Causes of Action alleged on behalf of a California State sub-class); and, (4) claims pursuant to theories of quasi-contract/unjust enrichment (Ninth Cause of Action). While all claims arise under state laws, federal jurisdiction is properly alleged pursuant to 28 U.S.C. §1332(d)(2).

Presently before the Court, upon referral by the Honorable Joanna Seybert, is Defendants' motion to dismiss the Amended Complaint, pursuant to Rules 12(b)(1) and 12(b)(6) of the Federal Rules of Civil Procedure. Also before the Court is Defendants' motion requesting that the Court take judicial notice of certain documents in connection with the motion to dismiss. The latter motion is granted to the extent that the Court has elected to consider the full label of the Product and a publication of the Food and Drug Administration (the "FDA") setting forth agency guidance as to labeling.

As to the motion to dismiss, this Court finds that the name "fish oil" is, as required by the Food Drug and Cosmetic Act, the Product's common name. Plaintiffs' proposition that it be labeled differently seeks to impose state law requirements that are preempted. All claims should therefore be properly dismissed. Additionally, Defendants' use of the fish oil name is in no way false or misleading, which further forecloses any state law claims on the merits. The motion to dismiss should be granted without leave to re-plead.

BACKGROUND

I. Procedural Background

Plaintiffs commenced this action on September 24, 2021. (DE [1].) On January 26, 2022, Plaintiffs filed an Amended Complaint. (DE [21].) On February 7, 2022, Defendants moved to dismiss the Amended Complaint. (DE [25].) The motion was fully briefed on March 23, 2022.

(DE [28].) On October 31, 2022, the District Court referred that motion to this Court for Report and Recommendation. (Electronic Order of Seybert, J., dated Oct. 31, 2022.)¹

II. Factual Background

A. The Parties

Plaintiff Baines is a resident of Rome, New York. She states that she has purchased the Product on numerous occasions over the three-year period preceding the filing of this lawsuit. (Am. Compl. ¶¶15-16.) Baines alleges that she believed that the Product “was actual fish oil containing DHA and EPA,” which, according to Baines, it is not. (Id. ¶17.) She states that she would not have purchased the Product, or would have purchased it on different terms, had she known the truth. (Am. Compl. ¶20.) Baines also states that if she knew that the marketing and sale of the Product was lawful and not misleading, and/or that she could rely on the labeling, she would consider purchasing the Product again. (Id. ¶21.)

Plaintiff Froning is a resident of San Diego, California. Like Baines, Froning alleges that she has purchased the Product over the past three years. (Id. ¶25.) Froning also believed that the Product “was actual fish oil containing DHA and EPA,” was misled by the labeling of the Product, and would consider purchasing the Product in the future if the labeling was not misleading. (Id. ¶¶26-32.)

Defendant Nature’s Bounty, Inc. is a New York corporation with its principal place of business in this District. (Id. ¶33.) “Nature’s Bounty” is alleged to be the “flagship brand” of the Defendant Bountiful Company, a family of wellness brands “committed to providing people with high quality products to complement their lifestyles and physical health.” (Id.) The Bountiful

¹ Defendants’ motion for judicial notice was administratively closed by the District Court on September 30, 2022. It was thereafter referred, along with the motion to dismiss, by the Order of October 31, 2022.

Company is a Delaware corporation with its principal place of business in this District. It is a “manufacturer, marketer and seller of vitamins, minerals, herbal and other specialty supplements.” (Id. ¶34.)

B. Scientific Material Discussed in the Amended Complaint

The Amended Complaint contains detailed factual information regarding the processing of fish oils for packaging in capsules that are marketed as dietary supplements. Terms used in the Amended Complaint include, inter alia, fish oil, omega-3 fatty acids, and omega-3 fatty acid ethyl esters. It explains different processing methods used to transform crude fish oil into products marketed as supplements that bear the name “fish oil.” Whenever the Amended Complaint refers to a scientific fact forming the basis of Plaintiffs’ claims, it references (mostly in footnotes) a variety of materials.

Some of the materials referenced in the Amended Complaint are articles published in scientific journals, and some are public documents disseminated by groups including the Food and Drug Administration (the “FDA”), the United States National Institutes of Health (the “NIH”), the World Trade Organization (the “WTO”), the United States Pharmacopeia (the “USP”), the Codex Alimentarius Commission (“Codex”), the Global Organization for EPA and DHA omega (“GOED”) and the United States Customs And Border Protection Agency (“CBP”). CBP is mentioned in the Amended Complaint because it is the agency responsible for interpreting the Harmonized Tariff Schedule of the United States (“HTS”). Plaintiffs also rely on what appear to be chapters or excerpts from scientific textbooks. Other references are websites for products that compete with the Product. Together, these materials are referenced in the Amended Complaint’s first forty-eight footnotes, which appear in the first twenty-four pages of the fifty-page Amended Complaint, which pleading consists of 187 paragraphs.

Pursuant to an Order dated November 2, 2022, all documents cited in the footnotes to the Amended Complaint were separately provided. As discussed below, each such document is properly considered in the context of this motion. While not every reference material is discussed in this Report and Recommendation, the Court has been careful to read all of these materials in the light most favorable to Plaintiffs, without acting as an expert in scientific fields such as chemistry, or as to the business and taxation of the commercial fishing industry. Where any such expertise is necessary, the Court has refrained from interpretation and applied only its own plain-language reading of each document in the light most favorable to the text of the Amended Complaint. The Court states the facts therein – not its own interpretation thereof.

It is important to note that where the text of a document relied upon does not support factual allegations of the Amended Complaint, or where the pleading selectively quotes from the reference, the Court properly considers the full text of the reference material when determining the plausibility of Plaintiffs' claims. See BYD Co., Ltd. v. VICE Media, LLC, 531 F. Supp. 3d 810, 817 (S.D.N.Y. 2021) (stating that where a document relied upon in a pleading contradicts allegations in the pleading, the court need not accept pleading allegations but may properly rely on the referenced document).

The Amended Complaint includes information organized into subject headings entitled: Omega-3 Fatty Acids, Fish Oil, Omega-3 Fatty Acid Ethyl Esters and the Trans-esterification Process. The basic facts necessary to understand the links between these terms and Plaintiffs' claims, while supported by hundreds of pages of scientific articles are, when considered through the lens of common-sense, not difficult to understand and can be readily applied to evaluate the pending motion. The Court's explanation of those facts follows.

1. Omega-3 Fatty Acids and Health Claims Related Thereto

Omega-3 fatty acids (“Omega-3’s” or “OM3’s”) are polyunsaturated carboxylic Acids. (Am. Compl. ¶ 36.) Among the eleven types of OM3’s, the three most important to human physiology are alpha-linolenic acid (“ALA”), docosahexaenoic acid (“DHA”) and eicosapentaenoic acid (“EPA”). (Id. ¶ 37.) To be used for something other than energy, ALA must first be converted into EPA or DHA. (Id. ¶ 38.) Thus, it is important for humans to ingest adequate amounts of the OM3’s known as DHA and EPA. The primary source of DHA and EPA are marine oils present in certain fatty fish, such as salmon and other seafood. (Id. ¶ 39.) Other foods containing these OM3’s are nuts, seeds, plant oils and certain fortified foods. (Id. ¶ 40 n.6 (referencing “2022 NIH Fact Sheet for Consumers” (hereinafter “NIH Consumer Fact Sheet”).))

Scientific studies support (although not conclusively) various health benefits attributable to ingestion of fish oil and fish oil supplements. (Id. ¶ 40; see generally NIH Consumer Fact Sheet.) Despite these findings, neither the NIH nor any United States governmental authority has declared any minimum daily requirement for DHA or EPA. (NIH Consumer Fact Sheet.) Nonetheless, it is clear that between 2017 and 2019, medical experts noted the benefit of eating one to two servings of fatty fish each week. (Am. Compl. ¶ 42.)

Relying on a scientific article entitled “A Comparison of Synthetic Ethyl Ester From Fish Oil vs. Natural Triglyceride Form” by Douglas Mackay, MD, (Id. ¶ 40 n.9 (hereinafter the “MacKay Article”)), the Amended Complaint states the “unfortunate fact” that Americans do not consume a sufficient amount of fatty fish necessary to maintain adequate levels of EPA and DHA. In response to this deficiency, health care professionals began recommending that Americans supplement their diets with fish oil. (Id. ¶ 43 n.9.) The MacKay Article notes that

contamination of oceans creates a potential health hazard associated with eating fish. Therefore, MacKay concludes that “fish oil supplements may well be the healthier choice.” (Id.)

In 2019, the FDA lent its limited support to health claims associated with the ingestion of fish oil and fish oil supplements. In an official agency statement, it announced that it would not object to the making of certain “qualified” health claims that consumption of the OM3’s EPA and DHA “in food or dietary supplements may reduce the risk of hypertension and coronary heart disease.” (Id. ¶ 42 and n.8 (hereinafter “FDA 2019 Heart Claim Announcement”).) The 2019 FDA Heart Claim Announcement states that while the overall evidence before the agency did not meet the “significant scientific agreement” standard required for an authorized health claim, it did meet the “credible evidence” standard for a qualified health claim in the labeling of conventional foods and dietary supplements. Thus, by June of 2019, the FDA made clear that it would take no enforcement action against labeling stating that:

- consuming EPA and DHA combined may help lower blood pressure in the general population and reduce the risk of hypertension. However, FDA has concluded that the evidence is inconsistent and inconclusive. One serving of [name of the food or dietary supplement] provides [] gram(s) of EPA and DHA;
- consuming EPA and DHA combined may reduce blood pressure and reduce the risk of hypertension, a risk factor for CHD (coronary heart disease). However, FDA has concluded that the evidence is inconsistent and inconclusive. One serving of [name of the food or dietary supplement] provides [] gram(s) of EPA and DHA;
- consuming EPA and DHA combined may reduce the risk of CHD (coronary heart disease) by lowering blood pressure. However, FDA has concluded that the evidence is inconsistent and inconclusive. One serving of [name of the food or dietary supplement] provides [] gram(s) of EPA and DHA;
- consuming EPA and DHA combined may reduce the risk of CHD (coronary heart disease) by reducing the risk of hypertension. However, FDA has concluded that the evidence is inconsistent and inconclusive. One serving of [name of the food or dietary supplement] provides [] gram(s) of EPA and DHA, and

- Research shows that consuming EPA and DHA combined may be beneficial for moderating blood pressure, a risk factor for CHD (coronary heart disease). However, FDA has concluded that the evidence is inconsistent and inconclusive. One serving of [name of the food or dietary supplement] provides [] gram(s) of EPA and DHA.

2019 FDA Health Announcement (Id. n.8).

In addition to allowing the above-referenced language, the FDA had, since 2004, exercised its enforcement discretion to allow for the making of the qualified health claim that “supportive but not conclusive research shows that consumption of EPA and DHA omega-3 fatty acids may reduce the risk of coronary heart disease under certain circumstances.” (Id.) Against the backdrop of these scientific findings, and the FDA’s announcement allowing certain health claims to be made in connection with the marketing of DHA and EPA via food and supplements, it is not surprising that many companies have entered the fish oil supplement market.

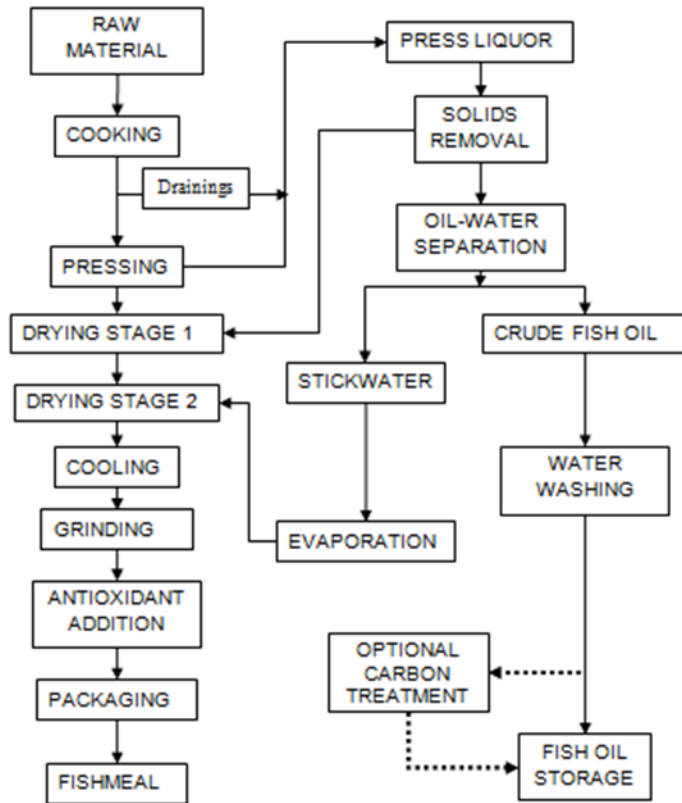
Plaintiffs’ claims do not (and, in light of the materials set forth in their pleading, could not) attack any health-related claim made by Defendants. Instead, they argue that the Product may not be called “fish oil” because of the molecular difference between the form of DHA and EPA contained in the Product. While it is not alleged that the Product is the only fish oil supplement containing this form of EPA/DHA, Plaintiffs draw a molecular distinction between the form contained in the Product and that found in other DHA/EPA fish oil supplements on the market. This molecular difference is attributable to the different methods used to extract and process fish oil. The Court turns to discuss those differences.

2. Fish Oil Extraction: Early Methods and the Current “Wet Reduction Process”

OM3’s (and more specifically to this matter, the OM3’s EPA and DHA) are found in a variety of foods, including the oil of fatty fish. (Am. Compl. ¶45.) The Amended

Complaint describes two different processes for extracting oil from such fish. These are processes for converting raw fish into fish oil that can be placed in capsules that are marketed as dietary supplements. First, the Amended Complaint describes a process that has been used, in one way or another, since the 1800's. Pursuant to that early process, caught fish were cooked "and a rock weighted process was used to press oil from the fish." (Id.) Later on – but still more than 100 years ago – "the rock weighted process was replaced with a hydraulic press." (Id. ¶ 45 and n.13 (referencing H. Breivik, Long-chain Omega-3 Specialty Oils, Woodhead Publishing in Food Science, Technology and Nutrition, at 11).)

The Amended Complaint goes on to state that, today, a process to extract fish oil from fish, known as the "wet reduction process," "remains relatively the same." (Id. ¶ 46.) Thus, after being caught, fish are "on-boarded to a fishing vessel and quickly boiled." (Id. ¶ 46.) The fish are then "cooked and pressed, separating the water and oil from proteins and solids." (Id.) Today, in addition to the mechanical pressing of fish, the wet reduction process requires the additional steps of separating water from the oil and "a polishing process," which includes "de-acidifying, degumming, and washing the oil several times." (Id. ¶ 46.) The Amended Complaint also describes the next parts of the wet reduction process. These additional steps involving further processing and purification. (Id. n. 21 (hereinafter "Science-based Health").) These steps require that after pressing, fish oil must be bleached and deodorized. (Id. ¶ 46 and n.17.) The washing and bleaching processes do not remove cholesterol, saturated fatty acids or contaminants like heavy metal, dioxins or pesticides. The wet reduction process is described in graphic form in the following flow chart appearing in the Amended Complaint:



(Id. n.14.) The original flowchart appears in Bimbo, A. (2011) Marine oils; edible oil processing, AOCS Lipid Library, December 2016 (“Bimbo Article”). The Bimbo Article also describes in detail the “cooling and stabilization” phases of fish oil processing. This involves the use of an anti-oxidant. While tocopherols may be used for this process, Bimbo also refers to “ethoxyquin” (a synthetic chemical food preservative) as the oxidant of choice. Bimbo also states that if contaminants such as dioxins are noted to be present, a carbon treatment may be added as an additional optional processing step. In addition to the wet reduction process, the Bimbo Article describes several other methods used to extract fish oil, but a description of these other processes is not necessary to consider in the context of the present motion.

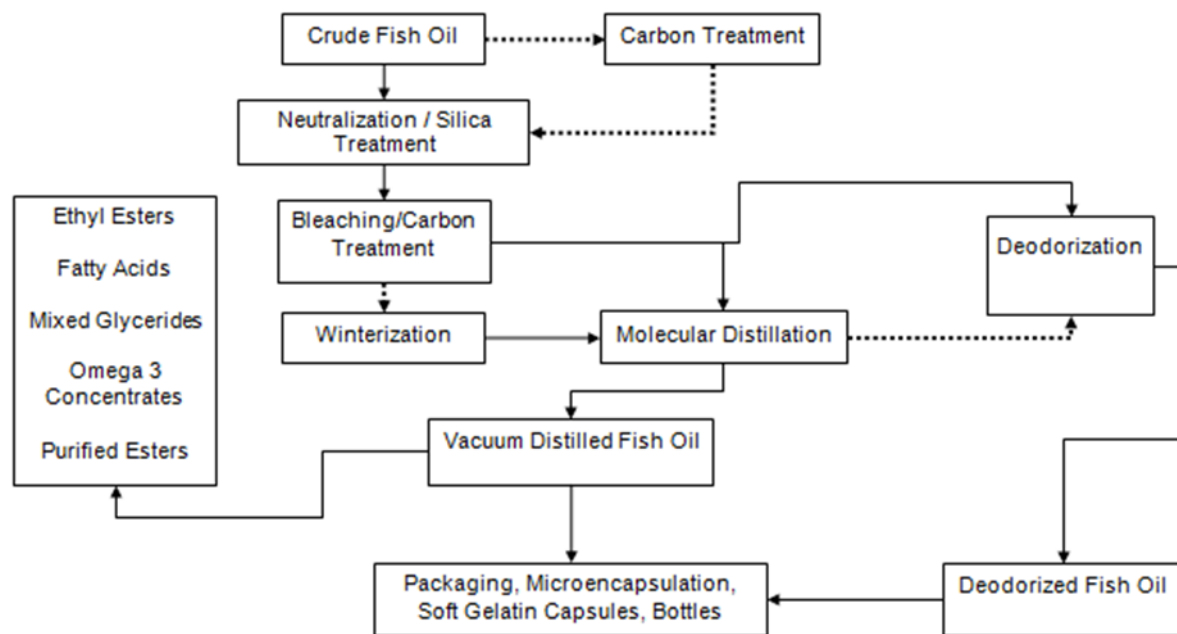
The Amended Complaint stresses that the wet reduction process described above is critical to understand, because it is a physical extraction method that differs from another method used to extract fish oil, which Plaintiffs characterize as a chemical process. This distinction is

central to Plaintiffs' case, because it is the molecular differences that result from the latter process for fish oil extraction that forms the basis for their claims that the Product may not bear the name "fish oil." Before evaluating this claim for plausibility, the Court turns to a discussion of the information the Amended Complaint addresses under sections entitled "OM3 Fatty Acids Ethyl Esters" and "The Trans-Esterification Process." The latter is the name for the alleged chemical process that forms the basis of Plaintiffs' claims that DHA and EPA extracted via the trans-esterification process may not be called "fish oil."

3. Ethyl Esters and Trans-Esterification

Triglycerides are formed by fatty acids (such as DHA and EPA) that, as a matter of chemistry, are bound to a glycerol "backbone." This is a molecular "backbone," not the backbone of any fish. Unrefined fish oil contains triglycerides with varying amounts of DHA and EPA. In or around the 1980's, scientists developed a process known as "trans-esterification" as a method of freeing DHA and EPA from glycerol. Use of this process increases the concentration of DHA and EPA in fish oil. (Am. Compl. ¶ 50.) It also allows for manipulation of amounts of these OM3's. Specifically, trans-esterification involves removing the glycerol molecular "backbone" from DHA and EPA. The glycerol is removed by introduction of ethanol, which frees the EPA and DHA from the glycerol. In a subsequent process known as "molecular distillation," the mixture is heat distilled resulting in a "condensate omega-3 ethyl ester solution." (Id. ¶ 52; Science-based Health; McKay Article.)

Like its description of the wet reduction process, the Amended Complaint contains a flow chart describing the trans-esterification process:



While this process includes additional steps, it also starts with crude fish oil. Both the wet reduction process and the trans-esterification process include the steps of bleaching and deodorization. (*Id.* ¶ 52.) The trans-esterification process, however, adds the additional molecular step of separating fatty acids from glycerol. As noted, this process can yield a product with higher levels of EPA and DHA, and levels of these OM3’s that can be separately manipulated. This allows for manufacture of a product containing more DHA and EPA, at a cheaper cost of production. (*Id.* ¶ 53.) It can also result in the production of an OM3 product with levels of DHA and EPA that may only be available via prescription. (MacKay Article.) Additionally, the trans-esterification process results in DHA and EPA free from mercury, which may remain present in DHA and EPA that were present in OM3’s derived via the process used in the 1800’s and today, via the wet reduction and other methods that leave the glycerol molecule intact.

4. Alleged Differences in the Forms of DHA/EPA Derived From Different Processes

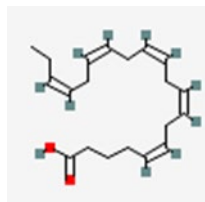
The Amended Complaint describes the DHA and EPA that are freed from the glycerol backbone through the trans-esterification process as “ethyl ester” DHA and EPA –

or, as described by Plaintiffs, as “DHA-EE” and “EPA-EE.” The literature notes that there are, indeed, different molecular level forms of DHA and EPA that are derived by the different methods used to process and purify raw crude fish oil into supplements. Plaintiffs argue that the only forms of DHA and EPA that may lawfully bear the “fish oil” name are those derived by a process that does not involve removal of the glycerol backbone of the molecule, which they refer to as DHA/EPA “triglycerides” or DHA/EPA-“G.”

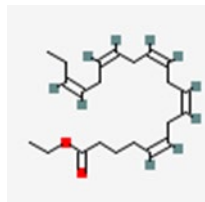
The Court's review of the reference material contained in the Amended Complaint reveals the limited scientific use of the addition of the “EE” to the terms DHA and EPA to identify ethyl esters. However, these distinctions appear either as background information (noting that most fish oil products on the market use the ethyl ester form), in connection with the claim that DHA/EPA derived via trans-esterification allows for products with higher levels of these OM3's, or in a study evaluating whether one offers more health benefits than the other (no conclusive study shows, by the way, any such difference). (*Id.* n.17 (NIH Omega-3 Fatty Acids Fact Sheet for Health Professionals (hereinafter “NIH Professional Fact Sheet”) (discussing dietary supplements and stating that there is no scientific question but that “consumption of all forms [of DHA/EPA] significantly increase plasma” EPA and DHA)) (emphasis added).

Despite the fact that the scientific literature relied upon in the Amended Complaint makes no distinctions between the forms of DHA/EPA as to efficacy, Plaintiffs properly plead that there are, indeed, molecular differences between these forms. Thus, the MacKay Article notes that while there were hundreds of fish oil supplements available, these supplements were made up of “two distinctly different molecular forms of fish oil supplements; one containing “synthetic” ethyl esters and one containing “natural” triglycerides.” (MacKay Article) (emphasis added).

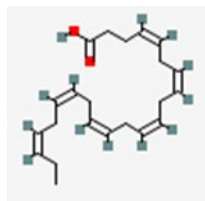
Plaintiffs' claims regarding molecular differences is also supported by an image of side by side molecular structures of DHA and EPA, which concludes that the molecules are "distinct in every regard," noting that "they have different molecular weights, chemical structures, physical properties and common/usual names." (Am. Compl. ¶ 57.)



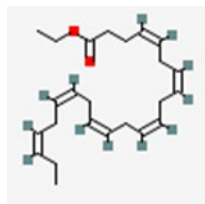
Chemical Structure of EPA



Chemical Structure of EPA-EE



Chemical Structure of DHA



Chemical Structure of DHA-EE

Discerning the differences among these chemical structures is challenging. However, given enough time, chemists and most observers would be able to see them.

After observing these molecular-level differences, the MacKay Article poses the question whether these two divergent “delivery forms of DHA and EPA produce a meaningful difference in the bioavailability of Omega-3’s to the body.” (MacKay Article) (emphasis added). MacKay concludes that it is “difficult to establish conclusively their relative bioavailability” and that early “small trials revealed that DHA and EPA from ethyl esters are well absorbed when compared to triglycerides.” (Id.) McKay notes, after reviewing inconclusive studies, and considering the fact that most DHA/EPA products are synthesized using the ethyl ester process, that he finds no difference between the use of the two forms of OM3’s as supplements. Indeed, McKay goes on to state that “most consumers and health care professionals are unaware that there are two different delivery forms of these valuable nutrients.” (Id.) (emphasis added).

Ultimately, no scientific literature annexed to the Amended Complaint takes the position that one form of DHA/EPA is superior to the other from a health perspective (except for the possible presence of mercury in the triglyceride form). Indeed, the Court has reviewed all of the scientific materials referenced in the Amended Complaint and states confidently that neither the Amended Complaint nor any document referenced therein makes any claim that one form of fish oil (triglyceride or ethyl ester) is superior to the other as to an association with health benefits.

5. References to USP Mass Spectra Monograph

The Product is USP certified. Plaintiffs do not argue otherwise. However, in paragraphs 58-60 of the Amended Complaint, Plaintiffs refer to USP standards and to a USP monograph. Plaintiffs allege that the USP monograph lends further support to their molecular difference claims. Thus, they state that the monograph demonstrates that the different molecules (EPA/DHA (G and EE)) each have “a unique mass to charge ratio (m/z).” (Am. Compl. ¶ 60.) Plaintiffs support these claims with a “mass spectrograph” appearing at page twenty-one of their

Amended Complaint. Plaintiffs' graph of molecular mass spectra makes their previously discussed flow charts and chemical structure models look downright simple. However, for purposes of this motion, it is necessary only that the Court accept this material as further support for Plaintiffs' claims as to the molecular differences previously discussed.

6. CODEX and Tariff Documents

Plaintiffs refer and rely upon the Codex, GOED and CBP tariff documents in support of their factual allegations. Codex standards are voluntary and are used by the WTO as a benchmark for global trade disputes. (*Id.* ¶ 62.) Section 2.2 of the Codex standards defines "fish oils" as "those derived from one or more species of fish or shellfish." Section 2.6 of that document defines "concentrated fish oils ethyl esters" as those derived from fish oils composed primarily of fatty acids ethyl esters. (*Id.* ¶ 62 n.37.)

GOED is a trade group stated to be "the largest and most significant trade group" of the OM3 industry. A voluntary monograph of that industry is stated to refer to such OM3's by a series of different names, including "refined EPA and/or DHA Omega-3 Oils triglycerides, EPA and/or DHA Omega-3 Oils Ethyl-Ester Concentrates, EPA and/or DHA Omega-3 Triglycerides Concentrates, Tuna Oil, Salmon Oil and Anchovy Oil." Plaintiffs argue that these trade organization references are further confirmation that "fish oil is not synonymous with fatty acid ethyl esters and cannot be so named." (*Id.* ¶ 66.)

Finally, in support of Plaintiffs' claims as to the alleged clear differences between EPA/DHA as triglycerides and DHA/EPA as fatty acid ethyl esters, the Amended Complaint relies on a 2011 CBP tariff decision as to the proper duty rate to be applied to the importation of fish oil ethyl ester capsules. (*Id.* ¶ 70.)

III. Plaintiffs' Causes of Action: The Amended Complaint

The Amended Complaint sets forth nine state law claims under the common and statutory laws of the States of New York and California. Plaintiffs seek certification of sub-classes and relief in the forms of disgorgement of profits, compensatory, statutory and punitive damages. They also seek injunctive relief, costs and attorney's fees. (See generally id. ¶¶115-187; Prayer for Relief.)

Given the detailed scientific information discussed above, it comes as no surprise that all claims are based upon molecular differences observable in products derived from different methods for the processing of fish oil. It is equally unsurprising that Plaintiffs nowhere argue that Defendants make false claims about the health benefits of their Supplement. Any such claim is directly contradicted by Plaintiffs' many reference materials. Further, Plaintiffs have no quarrel with use of the name "fish oil" in connection with the marketing of omega-3 fatty acid DHA and EPA products derived using the wet reduction process (which OM3's they variously refer to as EPA and DHA with the addition of the letter "G" for triglyceride). It is just the OM3's derived via the trans-esterification process that Plaintiffs state may not lawfully bear the name "fish oil." Thus, Plaintiffs frame their argument for falsity as follows:

Ultimately, once trans-esterified, fish oil is substantially and irrevocably transformed into an Omega-3 fatty acid ethyl ester – a [] that cannot be found in any part of a fish. Calling it "fish oil," therefore, is fraudulent, deceptive and misleading.

(Id. ¶ 55.)

The blank space above does not appear in the Amended Complaint – it is supplied by the Court because the sentence, as it appears in Paragraph 55 of the Amended Complaint, is not a full sentence. (Id. ¶ 55.) It is possible the existence of a partial sentence appears intentionally for dramatic effect, but that is not at all clear. The Court reasonably presumes that the blank space is

a typographical error, and given the opportunity to fill the blank, Plaintiffs would insert a word such as “substance” or “molecule.” The Court will construe the sentence as such and presume that, given the overall gist of the Amended Complaint, Plaintiffs are alleging that once transesterified fish oil is transformed into fatty acid ethyl esters, which are not natural and/or the same as the molecules derived from a different process. Thus, Plaintiffs’ case turns on the argument that the freeing of fatty acids from the glycerol backbone of the OM3 molecule transforms the Product away from “fish oil” into “omega-3 fatty acid ethyl esters,” which they define as “fish oil and omega-3 fatty acid ethyl esters.” (*Id.* ¶ 56.) The Product is stated to have been transformed from something that can commonly be called “fish oil” into a substance with a different “common or usual name,” presumably an “omega-3 fatty acid ethyl ester.” (*Id.*) All of Plaintiffs’ claims turn on acceptance of this molecular distinction.²

IV. The Motion to Dismiss

Defendants move, pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6), to dismiss the Amended Complaint in its entirety. First, Defendants argue that Plaintiffs’ claims are completely preempted by Federal Law, which forecloses application of any state labeling requirement that is “not identical” to federal labeling requirements. They argue that since Federal law requires that dietary supplements be labeled according to their “common” or “usual” name,

² This case is not the only one commenced by Plaintiffs’ counsel alleging that the use of the term “fish oil” is false and misleading. A case alleging the same theory was commenced by Plaintiffs’ counsel in the United States District Court for the Central District of California. See Gatto v. Int’l Vitamin Corp., No. 21-889 (JLS-DFM). That case, recently dismissed without prejudice on grounds not applicable here, was also styled as a class action brought on behalf of members of putative New York and California sub-classes. The New York plaintiff in that case resided in Massapequa, New York, which is in the Eastern District of New York, while the New York Plaintiff here also resides in New York, but in a different District.

which in this case is unquestionably “fish oil,” any application of state law requiring something different is preempted.

Defendants also argue that their labeling of the Product is not misleading as a matter of law. According to Defendants, no reasonable consumer could make a distinction between fish oil derived from a mechanical or chemical process. Moreover, to the extent any consumer was aware of any such difference, the label for the Product does in fact disclose that the OM3’s contained therein are derived as ethyl esters. Plaintiffs oppose the motion in its entirety.

Having explained Plaintiffs’ claims and the motion, the Court turns to the merits of the present motion to dismiss.

DISCUSSION

I. Legal Principles

A. Standards on Defendants’ Rule 12 Motions to Dismiss

Defendants move to dismiss, pursuant to Rules 12(b)(1) and 12(b)(6), the Amended Complaint in its entirety. The standards that apply to their Rule 12(b)(1) motion are not distinguishable in this case from their Rule 12(b)(6) motion. No party argues otherwise.

To survive a Rule 12(b)(6) motion to dismiss, a complaint must contain “sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible on its face.’” Ashcroft v. Iqbal, 556 U.S. 662, 678-79 (2009) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007)); see also Arista Records, LLC v. Doe 3, 604 F.3d 110, 119-20 (2d Cir. 2010). Facial plausibility is established by pleading factual content sufficient to allow a court to reasonably infer the defendant’s liability. Twombly, 550 U.S. at 556. “Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice.” Id. at 555. Nor is a pleading that offers nothing more than “labels and conclusions” or “a formulaic recitation of the

elements of a cause of action,” sufficient. Iqbal, 556 U.S. at 678 (2009) (quoting Twombly, 550 U.S. at 555). As required in the context of this motion to dismiss, the factual allegations in the Complaint, though disputed by Defendants, are accepted to be true for purposes of this motion, and all reasonable inferences are drawn therefrom in favor of the Plaintiff.

B. Materials Considered

1. Footnote References

While facts to consider in the context of a Rule 12 motion are generally limited to those set forth in the pleadings, a court may consider matters outside of the pleadings under certain circumstances. Specifically, in the context of a Rule 12(b)(6) motion, a court may consider: (1) documents attached to the complaint as exhibits or incorporated by reference therein; (2) matters of which judicial notice may be taken; or (3) documents upon the terms and effect of which the complaint “relies heavily” and which are, thus, rendered “integral” to the complaint. Chambers v. Time Warner, Inc., 282 F.3d 147, 152-53 (2d Cir. 2002); see also International Audiotext Network, Inc. v. American Tel. and Tel. Co., 62 F.3d 69, 72 (2d Cir. 1995).

Here, the Amended Complaint references numerous documents in the footnotes therein. These materials are integral to the facts pled in support of Plaintiffs’ claims and are, therefore, properly considered. See Daniel v. Mondelez Int’l. Inc., 287 F. Supp. 3d 177, 183 (E.D.N.Y. 2018). While the footnotes contained in the Amended Complaint refer to hundreds of pages of materials, these materials are not separately filed on the docket. Nor are they filed so that they can be accessed by direct link to the Amended Complaint. While the reader can (sometimes) access the entirety of each reference by separately searching the internet, this access is insufficient to provide the ease of access required of Court documents. Nor does such access

ensure that the reader is evaluating the precise document upon which Plaintiffs rely – or what the document looked like on the date it was viewed. Therefore, to evaluate the merits of the present motion, this Court has required Plaintiffs to provide courtesy copies of all such documents. See Order of Shields, M.J., dated Nov. 2, 2022. Each referenced document will be considered in its entirety in connection with the motion. In addition, to ensure ease of public access to each document referenced in the footnotes to the Amended Complaint, the Court hereby requires that Plaintiffs file each such document, in full, on the docket herein within one week of the date of this Report and Recommendation.

2. Materials as to Which Judicial Notice is Taken

Defendants have also moved, separately, to have this Court take judicial notice as to certain material for consideration in connection with this motion. (DE [26].) That motion seeks to have the Court consider images of product labeling appearing in the Amended Complaint, images of product labels from publicly available websites, and the FDA’s Food Labeling Guide, available at the agency’s website. Like the motion to dismiss, the motion for judicial notice, was made on February 7, 2022. It was administratively terminated by the District Court in an Order dated September 30, 2022. The District Court stated that it would rule upon that motion together with Defendants’ motion to dismiss. See Order of Seybert, J., dated Sept. 30, 2022. The October 31, 2022 referral of the pending motion to dismiss also referred Defendants’ motion requesting judicial notice. See Order of Seybert, J., dated Oct. 31, 2022.

Plaintiffs have not responded to the judicial notice motion at all – either in a separate Memorandum of Law addressed to the motion, or in their Memorandum of Law submitted in opposition to Defendants’ motion to dismiss. As to the latter, a review of the table of contents therein reveals no reference to any case referred to in the motion for judicial notice. (DE [27] at

ii-vi.) In view of the foregoing, the Court recommends that the motion for judicial notice be granted to the extent that it refers to any such document herein, as both unopposed and on the merits. The Court's references to these materials is limited and not, standing alone, dispositive of the motion. Nonetheless, the Court recommends granting the motion for judicial notice as to the entirety of the label for the Product (Defendants' Request for Judicial Notice, Exh. A and C (DE [26-1], [26-3]) and to a publicly available statement on the FDA website providing labeling guidance regarding the use of scientific names to describe ingredients (Defendants' Request for Judicial Notice, Ex. D (DE [26-4])). The label appears as a website printout and is obviously proper to consider in light of the fact that its alleged falsity forms the basis of each and every claim. See Sola Franchise Corp. v. Solo Salon Studios, Inc., No. 14-CV-0946, 2015 WL 1299259, at *19 (E.D.N.Y. 2015) (taking judicial notice of material appearing on website). Judicial notice is also undoubtedly proper as to statements contained in FDA labeling guidance. See Richardson v. New York City Bd. of Educ., 711 F. App'x 11, 14 (2d Cir. 2017); In re Zyprexa Prods. Liab. Litig., 549 F. Supp. 2d 496, 501 (E.D.N.Y. 2008) (holding that public documents issued by government agencies such as the FDA may be judicially noticed). The Court has not referred to nor relied on the other document for which judicial notice is sought. (DE [26-2].) Therefore, it need not report and recommend as to whether that label is subject to judicial notice for the purpose of this motion to dismiss.

3. Alleged Violation of The District Court's Page Limitations

The Court makes clear that it has considered all pages of the parties' Memoranda of Law. Defendants seek to have the Court ignore the last three pages of Plaintiffs' opposition brief. Relying on the Individual Rules of the referring District Court (which limit opposition briefs "to 25 pages" "double spaced (no more than 23 lines/page)"), they note that

Plaintiffs’ opposition has “26 lines per page, netting an extra three pages (75 extra lines over 25 pages).” (DE [28] n.1.) While this appears to be true, Defendants should not be so quick to crow about their adherence to page limits. Their ten-page reply brief includes six single-spaced tiny-font footnotes containing significant legal argument. The inclusion of this material in the body of the Memorandum of Law would likely have doubled the size of the reply brief. This is equally true of Plaintiffs’ opposition brief, which includes seventeen single-spaced footnotes which likewise contain significant legal argument. The parties’ copious use of substantive footnotes clearly violates the spirit (if not always the letter) of Court-imposed page limitations.

Perhaps, if the parties had more time, they could have made their submissions shorter. In any event, this Court has considered all pages and all footnotes contained in all motion papers submitted in support of and in opposition to the referred motions.

DISCUSSION

I. Preemption

A. Legal Principles

The Federal Food Drug and Cosmetic Act (the “FDCA”) forbids the misbranding of foods and supplements by way of false or misleading labeling. See POM Wonderful, LLC v. Coca-Cola Co., 573 U.S. 102, 106 (2014). The Nutrition Labeling and Education Action (the “NLEA”) amends the FDCA to impose particular labeling requirements. It also contains a preemption clause that prohibits any state or political subdivision from imposing any labeling requirement “that is not identical to” those imposed by the NLEA. See 21 U.S.C. §343-1(a)(5). Preempted state-imposed labeling requirements include “any statute, standard, regulation, or other requirement that is issued by a State.” 21 C.F.R. §100.1(b)(5). This preemption provision also broadly includes common law duties. See Ackerman v. Coca-Cola, CV 09-0935, 2010 WL

2925955, at * 6 (E.D.N.Y. 2010). In the context of the NLEA, “not identical” means any requirement that directly or indirectly imposes obligations or contains provisions concerning the composition or labeling of food that differ “from those specifically imposed by or contained in the applicable [federal regulation].” 21 C.F.R. §100.1(c)(4); see, e.g., Brod v. Sioux Honey Ass’n Co-op., 895 F. Supp. 2d 975, 981 (N.D. Ca. 2012).

NLEA preemption does not foreclose any and all state law claims alleging false advertising or labeling. Thus, a plaintiff may pursue claims “to impose state-law requirements that are identical to those imposed by the FDCA or state-law requirements that are not related to areas already covered by the FDCA or federal regulation.” Chong v. Nestle Waters N. Am., Inc., CV 19-10901, 2020 WL 7690175, at * 3 (C.D. Ca. Nov. 30, 2020). Where, however, a plaintiff seeks to require labeling that is not identical to that required by federal law, any such claim is expressly and clearly preempted. See Riegel v. Medtronic, Inc., 552 U.S. 312, 330 (2008).

The NLEA regulation relevant here requires that a “statement of identity” appear on a packaging’s principal display panel. 21 CF.R. §101.3(a). That “statement of identity” must be set forth in terms of:

- (1) The name . . . specified . . . or required by any applicable Federal law or regulation; or, in the absence thereof,
- (2) The common or usual name of the food; or, in the absence thereof,
- (3) An appropriately descriptive term, or when the nature of the food is obvious, a fanciful name commonly used by the public for such food.

21 CF.R. §101.3(a) (emphasis added).

Here, the parties agree that there is no name for the Product that is specified or required by Federal law or regulation, which would trigger application of 21 CF.R. §101.3(b)(1). Thus,

the Product must bear its “common or usual name,” 21 C.F.R. §101.3(b)(2), if such common or usual name exists.

As to such “common or usual” names, the relevant Federal regulation provides that:

(a) The common or usual name of a food, which may be a coined term, shall accurately identify or describe, in as simple and direct terms as possible, the basic nature of the food or its characterizing properties or ingredients. The name shall be uniform among all identical or similar products and may not be confusingly similar to the name of any other food that is not reasonably encompassed within the same name.

21 C.F.R. §102.5(a) (emphasis added). Additionally, a “common or usual” name “may be established by common usage.” 21 C.F.R. §102.5(d).

B. Preemption Analysis

Turning to application of the preemption analysis, the first issue is whether the common name required by the NLEA is, as Defendants argue, “fish oil.” If it is, and Plaintiffs seek to prohibit the use of this name, their claims, however denominated, would amount to a request for non-identical labeling and would be preempted. In making the latter determination, it is important for the Court to state exactly what Plaintiffs’ claims are, and what they are not. This allows the Court to decide whether Plaintiffs seek to impose labeling that is “not identical” to the name required by the NLEA. But first, the Court must decide whether the Product’s common name is fish oil. It undoubtedly is.

1. The Common Name of the Product is Fish Oil

The Product is a supplement processed from the oil of fish. As such, common sense dictates that it should be called fish oil. The Court’s holding as to this common name is supported not only by a common sense reading of the facts set forth in the Amended Complaint, but also by the fact pleaded therein. Thus, “fish oil” is the name used in nearly every reference set forth therein. To be sure, many reference materials support Plaintiffs’ scientific

explanation regarding molecular differences between different forms of DHA/EPA. All agree that such differences exist. Such differences are described as differences in “delivery forms” not as different end products. See MacKay Article at 1. A close review of each of Plaintiffs’ references also demonstrates that, with the exception of references that refer only generally to DHA and EPA, everyone refers to all OM3 DHA/EPA products – however derived – as “fish oil” or fish oil supplements. The Court’s reference to “everyone” includes the FDA, the NIH, MacKay, Bimbo, other scientists referred to in the Amended Complaint, trade organizations and taxing authorities – they all use the term fish oil. See McKay Article at 1; Science Based Health; Bimbo Article; Breivik Article. While some of these scientific reference materials speak to molecular-level differences, none rely on these differences to describe a “common name” for an Omega 3 supplement as anything other than fish oil. Indeed, the Court cannot locate a single reference that uses the term ethyl ester (or any of the possible name combinations discussed below) in connection with discussion of a supplement, without also using the common name “fish oil.” Even the trade-related documents (which the Court holds are of limited relevance to the issue of a common name addressed to consumers), use the term “fish oil” when describing OM3 supplements. While some documents use the term ethyl ester, even those documents also use the term fish oil. In sum, all of the documents relied upon by Plaintiffs, and reviewed by the Court, uniformly support a holding that all DHA/EPA supplements – however derived from the original crude fish oil – are properly referred to as fish oil. No issue of fact is raised to the contrary.

The Court further notes that while Plaintiffs argue against the use of “fish oil” to describe the Product, they do not really offer a more “common or usual” alternative. Thus, they fail to show the common usage of any name other than fish oil, as set forth in 21 C.F.R. §102.5(a). It

seems that Plaintiffs would have the product labeled as “DHA-EE and EPA-EE” or as “omega-3 fatty acid ethyl ester” or as “Omega-3 FAEE,” or as “Omega-3 EPA-EE and DHA-EE” or perhaps just as “FAEE.” But they cite to no product on the market bearing such names, and there are no less common names imaginable for the Product. Acceptance of Plaintiffs’ argument – even beyond the pleading stage – would require this Court to order the opposite of what the NLEA requires – substitution of a product’s common name by a confusing description of its molecular structure.

Despite their detailed scientific pleading – complete with sophisticated articles, flow charts, chemical structure pictures and complicated graphs, Plaintiffs fail to raise an issue of fact as to the common or usual name for the Product. That name is, without question, fish oil. The minutiae of scientific articles discussing molecules does not change that. If it did, the FDA would not state, as it does, that marketers are to avoid the use of an ingredient’s chemical name instead of its common name. Instead, it would advise that labels include information regarding molecular structure. Thus, for example, the FDA’s food labeling guide advises the use of the common term “sugar” instead of the scientific name “sucrose.”

<https://www.fda.gov/files/food/published/Food-Labeling-Guide-%28PDF%29.pdf> (Defendants’ Request for Judicial Notice, Ex. D, DE [26-4]). Where, as here, there is no claim that molecular differences matter, such information would not be helpful to consumers. It is therefore not surprising that no such information is required.

Finally, the Court recognizes that other courts have rejected similar “common name” arguments, holding that that any such requirement is preempted. Thus, in Regan v. Sioux Honey, 921 F. Supp. 2d 938, 943-44 (E.D. Wisc. 2013), the Court held that preemption applied where state law would prohibit a product to be labeled by its common or usual name, which was

undoubtedly “honey.” Accord Brod, 895 F. Supp. 2d at 981(finding that the product’s common or usual name is simply “honey” even though it has been filtered to contain no pollen); Birmingham v. Walgreen Co., 12-60922-Civ, 2014 WL 12479929, at *2-3 (S.D. Fla. Jan. 3, 2014).

Similarly, in Branca v. Bai Brands, LLC, 3:18-cv-00757, 2019 WL 1082562, at *5 (S.D. Ca. Mar. 7, 2019), the court rejected plaintiff’s attempt to draw a distinction in labeling based upon a difference observable only on a molecular level. Thus, it rejected the argument that the common name for “malic acid” must reflect a particular isomer thereof known as “d-1 malic acid.” Instead, the court held that the “common and usual name” of the ingredient is “malic acid” rather than the “scientific name of ‘d-1 malic acid.’” Id.

2. Plaintiffs Seek To Require Labeling That is Not Identical to NLEA Labeling

Plaintiffs’ claims, however denominated, are clear. They seek to bar Defendants from the use of the term “fish oil” to describe the Product. This would require Defendants to call the Product something other than fish oil. To be clear, Plaintiffs single out DHA/EPA OM3’s that are derived via the esterification process as those that may not lawfully bear the common name “fish oil.” The narrow nature of Plaintiffs’ claim is clear. They steer away from making the argument that one form of DHA/EPA is “healthier” than the other. Plaintiffs are also careful not to extend their argument to include the claim that no supplement on the market may use the common name “fish oil.” The Amended Complaint states clearly that Plaintiffs believed the Product “was actual fish oil containing DHA and EPA.” (Am. Compl. ¶ 17 (Baines), ¶ 26 (Froning).) Thus, they would not be confused as to the nature of such a product. Plaintiffs are comfortable with other supplements that contain EPA and DHA using “fish oil” as their common or usual name. Plaintiffs single out as falsely labeled only those

products (including Defendants’) that derive their fish oil through a particular process. All of Plaintiffs’ claims turn on the fact that there is a molecular difference between the DHA/EPA that are derived by freeing of the glycerol molecule, and the DHA/EPA that are derived via processes that do not free fatty acids from glycerol. The latter may bear the common name moniker “fish oil;” the former may not. Further, according to Plaintiffs, the former (including Defendants’ Product) has no “common or usual name,” and even if such name exists, it cannot be “fish oil.”

The Court’s holding is that the common name of the Product, and all OM3 supplements – however derived from fish oil – are required to bear the common name fish oil. This holding, taken together with the unquestionable nature of Plaintiffs’ claim, i.e., they seek to prohibit the use of this name for certain OM3 supplements, leads to the conclusion that they seek to impose a labeling requirement that is “not identical” to Federal law. As such, their claims are preempted. Even if Plaintiffs’ claims were not preempted, they are all implausible and should be dismissed.

II. Plaintiffs Also Fail to State a Plausible Claim Under Any State Law

A. Consumer Protection Laws of California and New York

Plaintiffs bring their claims under the state laws of California and New York. This Court’s preemption analysis disposes of all such claims. Even if it did not, Plaintiffs would nonetheless fail to state any claim. This is true whether their claims arise under California or New York statutory or common laws.

Plaintiff’s putative California sub-class seeks relief pursuant to three different California statutes. All are governed by a “reasonable consumer” test, requiring a showing that “members of the public are likely to be deceived.” Branca, 2019 WL 1082562, at * 9. This standard requires a probability “that a significant portion of the general consuming public or of targeted consumers, acting reasonably under the circumstances, could be misled.” Id. (citation omitted).

More specifically, Plaintiffs must plausibly allege “more than a mere possibility that the advertisement might conceivably be misunderstood by some few consumers viewing it in an unreasonable manner.” Id.

Plaintiffs’ putative New York sub-class seeks statutory relief pursuant to Sections 349 and 350 of the General Business Law. The standards applicable to these claims are substantially similar to the California claims. Thus, Section 349 prohibits “[d]eceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in this state.” N.Y. Gen. Bus. Law § 349. Section 350 similarly prohibits “[f]alse advertising in the conduct of any business, trade or commerce or in the furnishing of any service in this state.” N.Y. Gen. Bus. Law § 350.

To assert a claim under either Section 349 or 350, “a plaintiff must allege that a defendant has engaged in (1) consumer-oriented conduct that is (2) materially misleading and that (3) they suffered injury as a result of the allegedly deceptive act or practice.” Nguyen v. Algenist LLC, 22 Civ. 13, 2022 WL 17251733, at * 5 (S.D.N.Y. Nov. 28, 2022) (quoting Orlander v. Staples, Inc., 802 F.3d 289, 300 (2d Cir. 2015)) (additional citation omitted). The alleged deceptive act be a representation or an omission. See Nguyen, 2022 WL 17251733, at *5. The deception alleged “need not reach the level of common-law fraud to be actionable,” and therefore “deceptive business practice and false advertising claims are not subject to the heightened pleading requirements of Federal Rule of Civil Procedure 9(b).” Id. (citations omitted); see also Cooper v. Anheuser-Busch, LLC, 663 F. Supp. 3d 83, 93-94 (S.D.N.Y. 2021).

While factual allegations need not be pleaded in accord with the requirements of Rule 9(b), a material misrepresentation actionable under Sections 349 and 350 must be plausibly alleged as one that is “likely to mislead a reasonable consumer acting reasonably under the

circumstances.” Cohen v. JP Morgan Chase & Co., 498 F.3d 111, 126 (2d Cir. 2007) (quoting Oswego Laborers’ Local 214 Pension Fund v. Marine Midland Bank, N.A., 85 N.Y.2d 20, 26 (1995)); see also Orlander, 802 F.3d at 300. When considering this issue, courts consider the allegedly misleading statement in light of the context and the entirety of the label and/or advertising. See Belfiore v. Procter & Gamble Co., 311 F.R.D. 29, 53 (E.D.N.Y. 2015); Koenig v. Boulder Brands, Inc., 995 F. Supp. 2d 274, 288 (S.D.N.Y. 2014); Ackerman v. Coca-Cola, 2010 WL 2925955, at *15. Ultimately, the question is whether “a reasonable consumer in like circumstances would consider the misrepresentation material.” Daniel, 287 F. Supp. 3d at 189-90.

It is clear that whatever sub-class Plaintiffs seek to represent, their claims require a showing that reasonable consumers would be misled by labeling of the Product as fish oil. The Court holds, as a matter of law, that they would not. First, there is no falsity in calling the Product fish oil. Any such claim of falsity is implausible and therefore subject to disposition in connection with this motion to dismiss. As discussed above and in detail, in Plaintiffs’ pleading, their claims rise and fall on the notion that consumers would be misled by a difference observable only on a molecular level. It is implausible to believe that any consumer shopping for a fish oil supplement seeks only DHA/EPA with an intact glycerol backbone molecule. Moreover, even if such a consumer did exist – and the Court is unconvinced that any such person does – that consumer would see that the Product bears the common name of fish oil, and also discloses that the OM3’s therein are ethyl esters. Under these circumstances there can be no plausible claim that any reasonable consumer is misled. See Nguyen, 2022 WL 17251733, at *7 (noting that even if a consumer could be misled, clarifying information existed in packaging information as a whole).

Plaintiffs argue that the issue of reasonability presents a question of fact. However, this is not always the case, and a defendant should not be made to go to the expense of litigating patently implausible claims through discovery and the inevitable motion for summary judgment. “It is well settled that a court may determine as a matter of law that an allegedly deceptive advertisement [or label] would not have misled a reasonable consumer.” Kennedy v. Mondelez Global LLC, 19-CV-302, 2020 WL 4006197, at *9 (E.D.N.Y. July 10, 2020) (quoting Fink v. TimeWarner Cable, 714 F.3d 739, 741 (2d Cir. 2013)). “The standard is an objective one: ‘Plaintiffs must plausibly allege that a significant portion of the general consuming public or of targeted consumers, acting reasonably in the circumstances, could be misled.’” Kennedy, 2020 WL 4006197, at *11-12 (quoting Jessani v. Monini N. Am., Inc., 744 F. App’x 18, 19 (2d Cir. 2018) (quotations omitted)).

Courts have not hesitated to dismiss patently implausible false advertising claims on motions to dismiss. See, e.g., Nguyen, 2022 WL 17251733, at * 5; Kennedy, 2020 WL 4006197, at *11-12 (finding that terms “made with real honey,” “Honey Maid,” and “no high fructose corn syrup” did not misleadingly suggest that honey was the “exclusive or predominant sweetener”); Devane v. L’Oréal USA, Inc., No. 19-CV-4362, 2020 WL 5518484, at *1, 4-5 (S.D.N.Y. Sept. 14, 2020) (holding that a label that described a hair-care product as “100% Vegan” and “Keratin Caring” did not misleadingly suggest that the product itself contained keratin); Kommer v. Bayer Consumer Health, 252 F. Supp. 3d 304, 306, 311 (S.D.N.Y. 2017) (dismissing a claim that a “Foot Mapping Kiosk” misleads consumers into believing they are having custom orthotics designed for their feet), aff’d, 710 F. App’x 43 (2d Cir. 2018) (summary order); In re Frito-Lay N. Am., Inc. All Nat. Litig., No. 12-MD-2413, 2013 WL 4647512, at *16 (E.D.N.Y. Aug. 29,

2013) (observing that dismissal as a matter of law is appropriate where a plaintiff's allegations regarding deceptive labeling "border on fantasy").

While some cases present issues of fact as to falsity and reasonable interpretation by the reasonable consumer, this case falls squarely in the camp of those that do not. Here, Plaintiffs' claims are even less plausible than those dismissed in the cases described above. If it has not already been made clear, the Court states clearly here that there is nothing false about labeling the Product as fish oil. Describing the Product this way denotes nothing more than a statement of fact that the OM3's therein are derived from fish oil. It says nothing about the process by which crude fish oil makes its way to the OM3's found in each capsule. Plaintiffs do not, and cannot, argue that other supplements containing OM3'S derived from fish oil are properly named only if they are derived via a different process. All such products get their OM3's from fish oil. To suggest that molecular differences between such products make a difference to a reasonable consumer is plainly implausible. Thus, all claims alleging that a reasonable consumer would think otherwise are implausible and lacking completely in merit.

All of Plaintiffs' alleged statutory consumer protection claims, whether alleged pursuant to the laws of the States of New York or California, should be dismissed.

B. All Other Claims

Dismissal of Plaintiffs' claims on the grounds set forth above disposes of any and all of Plaintiffs' claims, whether arising under statutory or common law. To the extent the Court has not discussed common law claims, it makes clear now that all such claims are implausible and should be dismissed. See Wallace v. Wise Foods, Inc., 20-CV-6831, 2021 WL 3163599, at *3 (S.D.N.Y. July 26, 2021) (holding that dismissal false labeling claims as implausible requires dismissal of express warranty and unjust enrichment claims); Forouzesht v. Starbucks Corp., CV

16-3830, 2016 WL 4443203, at *4 (C.D. Cal. Aug. 19, 2015), aff'd, 714 F. App'x 776 (9th Cir. 2018) (finding same result applying California law); see also Nelson v. MillerCoors, LLC, 246 F. Supp. 3d 666, 679 (E.D.N.Y. 2017) (dismissing quasi-contract claim as duplicative of other dismissed alleged consumer deception claims); Ebin v. Kangadis Foods, Inc., 13 Civ. 2311, 2013 WL 6504547, at * 7 (S.D.N.Y. Dec. 11, 2013) (same). Indeed, Plaintiffs concur that this is the law, i.e., if their false labeling claims fail, so too do their state law claims for breach of warranty. (DE [27] at 10.)

Finally, even if Plaintiffs' claims had merit, they lack Article III standing to bring any claim for injunctive relief. Past purchasers, such as Plaintiffs here, cannot plausibly allege any future harm that could be redressed by a grant of injunctive relief. Pleading a possible future purchase based upon new labeling does not change this result. See Berni v. Barilla S.p.A., 964 F.3d 141, 147 (2d Cir. 2020); Barreto v. Westbrae Natural, Inc., 518 F. Supp. 3d 795, 809 (S.D.N.Y. 2021); Ashour v. Ariz. Beverages USA LLC, 19 Civ. 7081, 2020 WL 5603382, at * 4 (S.D.N.Y. Sept. 18, 2020).

RECOMMENDATION

For the foregoing reasons, the Court respectfully recommends that Defendants' motion for judicial notice be granted to the extent set forth above. The Court further respectfully recommends that Defendants' motion to dismiss be granted. While Plaintiffs have not sought leave to amend, the Court additionally recommends that any such request be denied as futile.

Finally, as set forth above, to ensure ease of public access to each document referenced in the footnotes to the Amended Complaint, the Court hereby orders Plaintiffs to file each such document, in full, on the docket herein within one week of the date of this Report and Recommendation.

OBJECTIONS

A copy of this Report and Recommendation is being provided to all counsel via ECF. Any written objections to this Report and Recommendation must be filed with the Clerk of the Court within fourteen (14) days of filing of this report. 28 U.S.C. § 636(b)(1); Fed. R. Civ. P. 6(a), 72(b). Any requests for an extension of time for filing objections must be directed to the District Judge assigned to this action prior to the expiration of the fourteen (14) day period for filing objections. Failure to file objections within fourteen (14) days will preclude further review of this report and recommendation either by the District Court or Court of Appeals. Thomas v. Arn, 474 U.S. 140, 145 (1985) (“[A] party shall file objections with the district court or else waive right to appeal.”); Caidor v. Onondaga Cnty., 517 F.3d 601, 604 (2d Cir. 2008) (“[F]ailure to object timely to a magistrate’s report operates as a waiver of any further judicial review of the magistrate’s decision”).

SO ORDERED.

Dated: Central Islip, New York
January 3, 2023

/s/ Anne. Y. Shields
ANNE Y. SHIELDS
United States Magistrate Judge